REMARKS

This paper is responsive to the Office Action mailed June 3, 2004. Presently, all claims 1, 2, 4-6, 13 and 14 stand non-finally rejected.

Claims 1, 2, 4 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys. According to the Examiner, Parker discloses the recited sheath, with the exception of using fluorinated ethylene propylene (FEP) as the polymeric material. Therefore, according to the Examiner, it would have been obvious to one skilled in the art to modify the polymeric material in Parker to be made of any suitable plastic for use in catheters, including FEP as suggested by Coneys.

Prior to responding to this rejection, Applicants wish to thank the Examiner for his cogent and thoughtful comments provided in the Office Action when explaining the basis for the rejections. In response to these comments, however, Applicants wish to re-emphasize their contention that prior to the present invention, it was neither known, nor obvious, to use FEP *highly loaded with radiopaque materials* as a distal tip on an introducer sheath. Such structure is not taught by the references of record, nor is it fairly suggested by such references.

The present invention is directed to an introducer sheath. In the embodiment of independent claims 1 and 14, the sheath comprises a shaft formed of fluorinated ethylene propylene, and a distal tip section at the distal end of the shaft. The distal tip section is also formed of fluorinated ethylene propylene, and contains between about 20% and 75% by weight (claim 1), or about 50 to 55% by weight (claim 14), of a radiopaque material. The shaft is distinctly less radiopaque than the distal tip section.

Since both the shaft and the tip are formed from the same base polymer, namely fluorinated ethylene propylene, a secure bond is formed therebetween. Those skilled in the art recognize that in a medical device such as an introducer sheath, it is important that a secure bond be formed between the main shaft body and the distal tip, in order to avoid the inadvertent dislodgment of the distal tip portion within the vasculature during use of the device. In addition, those skilled in the art recognize that a secure bond is formed when the

same or similar polymers are bonded together. Those skilled in the art also recognize that when dissimilar materials are joined, it is normally more difficult to form a secure bond.

In the Office Action, the Examiner emphasized that Coneys is merely being cited to teach the use of FEP in a medical tube, and that it is immaterial whether FEP is amenable to high loadings of radiopaque particles since Parker teaches high loadings of radiopaque particles in a polymeric sheath. Applicants fully understand the point that the Examiner is making with regard to the citation of the Coneys reference. Admittedly, the use of FEP in an introducer sheath is known. However, Applicants respectfully state that the present invention requires more than the mere substitution of FEP for other known polymers in an introducer sheath.

The present claims require that the distal tip section be amenable to high loadings of radiopaque particles. It is not sufficient to merely state that a certain polymer is known for general use in an introducer sheath. There must be some teaching, suggestion or other reason to believe that the selected polymer is capable of being highly loaded with radiopaque particles, and that the resulting polymer has sufficient structural integrity for its intended use. Neither of the cited references teaches or suggests the use of highly-loaded FEP. In fact, Coneys can be fairly read to teach away from the use of FEP as a highly loaded distal tip material. According to Coneys, when highly loaded FEP is used in a medical device, the highly loaded FEP layer is surrounded by a covering of virgin FEP. On the other hand, in the present invention, highly loaded FEP is used as a distal tip material in the absence of an outer support layer. The inventive arrangement provides a highly radiopaque structure that enables a key purpose of the invention to be realized, that is, to provide a distal tip section that can be precisely located by radiography. If the teaching of Coneys was followed, it would be necessary to embed the highly loaded FEP layer in a layer of virgin FEP. When a purpose of the highly loaded FEP layer is to permit precise readings by radiography, the use of the outer layer of virgin FEP runs counter to such purpose (since it is not radiopaque), and may very well destroy the purpose of using a highly loaded layer in the first place. At the very least, it would dilute the radiographic signal. Furthermore, there is no reason to believe that the Coneys structure (highly loaded FEP layer embedded in virgin FEP) would provide a sheath wherein the shaft is distinctly less radiopaque than the distal tip section, as recited in

independent claims 1 and 14. Accordingly, Applicants respectfully submit that the cited combination neither teaches nor suggests the present invention.

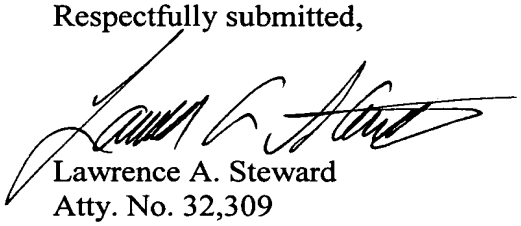
The Examiner also stated that even if Coneys was interpreted to require an outer layer of pure FEP in order to maintain structural integrity, as suggested by Applicants, that this would not destroy the combination since Applicants have claimed the structure using the open-ended term "comprising", rather than the closed-end term "consisting of." Although Applicants contend that the existing claims are presently allowable for the reasons provided above, Applicants have nevertheless added new claims 17-23 to the case to address this contention of the Examiner. As stated in new independent claim 17, the distal tip section "consist[s] essentially of" FEP containing high loadings of radiopaque material. With regard to new claims 17-23, it cannot be fairly said that Coneys teaches or suggests a distal tip of an introducer sheath that consists essentially of highly loaded FEP, because the "tip" in Coneys includes the virgin FEP. For this reason, Applicants submit that claim 17, as well as dependent claims 18-23 are also allowable over the references of record.

Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys and Hopkins. Claims 5 and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4 and 13 above, and further in view of Hopkins. Hopkins was cited for its teaching of the use of tungsten of a radiopaque material, and for teaching that such particles can be as small as 0.9 microns. Hopkins does not, however, teach the use of highly loaded FEP as a distal tip material. Thus, claims 5, 6 and 14 would be allowable for the same reason that the remaining claims are allowable.

Based upon the foregoing, Applicants respectfully submit that all claims 1, 2, 4-6, 13, 14 and 17-23 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that any issues

remain for resolution that are amenable to resolution by telephone conversation, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,



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